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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,878	02/02/2006	Andries Van Es	0807620.00111	9964
545 7550 03/24/2008 ROGER PITT KIRKPATRICK & LOCKHART PRESTON GATES ELLIS LLP 599 LEXINGTON AVENUE 33RD FLOOR NEW YORK, NY 10022-6030			EXAMINER TSAY, MARSHA M	
			ART UNIT 1656	PAPER NUMBER
			MAIL DATE 03/24/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/566,878

**Applicant(s)**

VAN ES ET AL.

**Examiner**

Marsha M. Tsay

**Art Unit**

1656

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7 and 9-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 9-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-856)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

In a telephone interview on March 6, 2008, Applicants' representative noted it was unclear whether the Office action of February 20, 2008 was a Final or Non-final action. The PTOL-326 inadvertently noted that the status of the February 20, 2008 action was Non-final; however, page 6 of the action noted that the action was Final. The previous action is withdrawn and the PTOL-326 has been corrected to reflect the correct status of the instant application.

This Office action is in response to Applicants' remarks received November 19, 2007. Claim 8 is canceled. Claims 1-7, 9-23 are pending and currently under examination.

Applicants' arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn.

Priority: The priority date is August 5, 2003.

### **Objections and Rejections**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 9 have been amended to recite the limitation as calculated using formula 8 and 9 in Y. Matveev et al. Food Hydrocolloids Vol. 11 no. 2, pp. 125-133, 1997. The incorporation of the reference in the claim is improper. Applicant is required to amend the claim to include the specific formulas disclosed in the Matveev et al. reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office.

Claims 2-7, 10-23 are included in this rejection because they are dependent on claims 1 and 9.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 9-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang et al. (WO 0134801; IDS) in view of Matveev et al. (1997 Food Hydrocolloids 11(2): 125-133; previously noted in 02/20/08 office action). Chang et al. disclose vaccines comprising recombinant gelatin and a method of producing such vaccines. Chang et al. disclose a dried vaccine formulation comprising recombinant gelatin (p. 85 line 9, p. 86 line 29; claims 1) or lyophilized vaccines comprising recombinant gelatin as a stabilizer (p. 61 lines 35-38; claim 1). Chang et al. disclose the recombinant gelatin can be derived from a human sequence or animal sources (p. 59 lines 16-19). It is known that gelatin comprises consecutive Gly-Xaa-Yaa triplets.

The recombinant gelatin can have a molecular weight range between 0 kDa to 350 kDa (p. 85 lines 22-26; claims 2-3). Chang et al. further disclose that the recombinant gelatin used for vaccine formulations have characteristics similar to those of animal-source gelatin, i.e. MW, melting temperatures, etc. (p. 65 lines 21-25).

Chang et al. also disclose a method of producing a composition comprising a vaccine and the recombinant gelatin (p. 88 lines 25-32; claim 9). In a non-limiting example, i.e. Example 4, Chang et al. disclose the expression of a non-hydroxylated recombinant human gelatin, which would inherently be free of a helical structure (p. 73 lines 5-10; claims 1, 6-8, 15-20). Further, Chang et al. disclose the recombinant gelatins can possess particular ranges of molecular weights (p. 63 lines 30-32, example 1; claims 5, 12-14). Chang et al. do not teach a glass transition temperature for gelatin.

Matveev et al. (1997 Food Hydrocolloids 11(2): 125-133) teach the glass transition temperature of gelatin is 200-217° C (p. 129, 132).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to produce a lyophilized composition comprising a vaccine and a recombinant gelatin derived from an animal source that is acceptable for consumption, such as the gelatin of Matveev et al., because Chang et al. disclose vaccines can be formulated from recombinant gelatin derived from an acceptable mammalian source (claims 1-7, 9-23). One of ordinary skill would recognize that the recombinant gelatin derived for vaccine formulation needs to be acceptable as a food protein in order to be safely administered to humans. Therefore, since Matveev et al. disclose gelatin is a food protein with a glass transition temperature of 200° C, one of ordinary skill would recognize that the food grade gelatin is derived from an animal source, and since the

recombinantly produced collagen/gelatin disclosed in Chang et al. can include gelatins derived from an animal source and have characteristics similar to those of animal-source gelatin, the recombinant gelatin of Chang et al. may have a glass transition temperature of 200° C even if not explicitly taught by Chang et al.

In their remarks, Applicants assert Chang et al. fail to teach the limitation wherein the recombinant polypeptide has a calculated glass transition temperature of higher than 180° C. Applicants further assert that Chang et al. disclose that any recombinantly produced collagen/gelatin can be employed as stabilizers in vaccine compositions, i.e. polypeptides of a wide variety of molecular weights, a wide degree of hydroxylation and/or cross-linking can be employed. Applicants also calculated the Tg of some of the gelatin sequences disclosed in Chang et al. (SEQ ID NOS: 15, 25, 30, 31, 33) and submit that the instant sequences do not have a Tg above 180° C. Applicant's arguments have been fully considered but they are not persuasive.

The instant claims are drawn to a lyophilized composition comprising an active substance and a recombinant gelatin polypeptide having a Tg of 200° C. As noted above, Chang et al. disclose a lyophilized vaccine comprising recombinant gelatin. As noted by Applicants' calculations, some of the gelatin polypeptides of Chang et al. do not appear to have a Tg of 200° C. However, disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). Therefore, while Chang et al. may disclose some gelatin polypeptides that lack a Tg of 200° C, Chang et al. also disclose that the recombinant gelatin used for vaccine

formulations have characteristics similar to those of animal-source gelatin, i.e. MW, melting temperatures, etc. (p. 65 lines 21-25). As evidenced and disclosed by Metveev et al., gelatin is a food protein that has a Tg of 200° C. Therefore, it would be reasonable for one of ordinary skill to recognize that food-grade gelatin is derived from an animal source. Furthermore, "[t]he prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed..." In re Fulton, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004). Chang et al. may disclose recombinant gelatin sequences that lack a Tg of 200° C, but the reference also discloses an alternative, that the recombinant gelatin used in a lyophilized vaccine formulation can be derived from animal sources and have characteristics similar to those of animal-source gelatin, which as disclosed by Metveev et al. would have a Tg of 200° C.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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February 14, 2008